

DETAILED ACTION

This application is a 371 (national stage application) of PCT/JP04/10758, filed on 7/22/2004.

Priority

This application, filed on 1/19/2006, also claims foreign priority to Application No. 2003-201549, filed on 7/25/2003.

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/8/2010 has been entered.

Response to Remarks

2. Claims 1, 8-9, and 53-58 were pending as of the response filed on 6/8/2010. The claim amendments filed on 6/8/2010 are sufficient to overcome the rejection under 35 USC 103(a) as being unpatentable over Greenlee et. al., in view of Shimada et. al. The Applicants have shown that the combination of a compound of formula (I) with paroxetine or fluoxetine, or a pharmaceutically acceptable salt or hydrate thereof, within the claimed concentration ranges, has a more than additive beneficial effect for treating

depression, which is unexpected over the prior art. The rejection under 35 USC 103(a) is withdrawn, and claims 1, 8-9, and 53-58 are allowed. A statement of reasons for allowance is disclosed below.

Statement of Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance: there is no prior art which teaches or suggests the combination of (E)-8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione and fluoxetine or paroxetine, or a pharmaceutically acceptable salt or hydrate thereof, within the claimed concentration ranges, for a greater than additive effect for the treatment of depression. The closest prior art is Greenlee et. al., WO 03/022283 Patent Publication, and Shimada et. al., WO 99/12546, in which the English version US Patent No. 6,727,259 is referenced for convenience (both of previous record). Greenlee et. al. teaches the combination of an adenosine A2A receptor antagonist and selective serotonin reuptake inhibitors, such as fluoxetine for the treatment of depression, while Shimada et. al. teaches that (E)-8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione is an adenosine A2A antagonist with anti-depressant activity. However, there is no suggestion by either reference to specifically combine (E)-8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione with fluoxetine or paroxetine for the treatment of depression, or that such a combination would have a greater than additive benefit. Claims 1, 8-9, and 53-58 are novel and non-obvious over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 3/3/2010 was filed after the mailing date of the final office action on 10/20/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Conclusion

5. Claims 1, 8-9, and 53-58 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 7:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627